

**LIBELED:** 5-16-61, Dist. P.R.

**CHARGE:** 503(b)(4)—when shipped, the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 8-3-61. Default—destruction.

**6789. Hy-Jet Wafers, Medcol Cotabs, and Medatinic tablets.** (F.D.C. No. 45895. S. Nos. 31-330 R, 31-332/3 R.)

**QUANTITY:** 17,580 *Hy-Jet Wafers* in btls. of 12 wafers, 24 wafers, and 500 wafers; 50,000 tablets of *Medcol Cotabs* in bulk containers and an undetermined number of 100-tablet btls. of *Medcol Cotabs*; and approximately 20,000 tablets of *Medatinic tablets* in 100-tablet btls., at New Orleans, La., in possession of Medco Co., Inc.

**SHIPPED:** The *Hy-Jet Wafers* were shipped on 2-12-60, from Gardena, Calif., by S. O. Barnes & Son, Inc.; and the other articles were shipped by a different firm, from Memphis, Tenn., on 12-11-59 and 12-28-59.

**LABEL IN PART:** (Btl.) "A New Concept in Feminine Hygiene *Hy-Jet Wafers* \* \* \* buffered to maintain an acid condition in the vaginal mucosa \* \* \* Medco Company, Inc., New Orleans, Louisiana"; "100 Cotabs MEDCOL \* \* \* Each Cotab contains: Pyrilamine Maleate 4 mg., Metapyrilene HCl 4 mg. \* \* \* Caution:"; and "100 Tablets Medatinic 500 Mg. Each Tablet Contains: Nicotinic Acid 500 Mg. (Niacin) \* \* \* Mfg. for Medco Co., Inc., New Orleans, La."

**RESULTS OF INVESTIGATION:** Analysis of the *Hy-Jet Wafers* showed that they contained boric acid and phenylmercuric borate in an effervescent base. The other articles were assumed to contain the ingredients listed on their labels. The *Medcol Cotabs* and the *Medatinic tablets* contained in the bottles had been repacked by the dealer from bulk containers shipped as described above.

**LIBELED:** 5-24-61, E. Dist. La.

**CHARGE:** 502(a)—when shipped, the label of the *Hy-Jet Wafers* contained false and misleading representations that the article was adequate and effective for the treatment of monilia, trichomonas, staphylococcus, and streptococcus infections of the vaginal tract; and 503(b)(4)—while held for sale, the label of the *Medcol Cotabs* bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not subject to 503(b)(1); and 503(b)(4)—while held for sale, the *Medatinic tablets* were a drug subject to 503(b)(1) and their label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** *Medcol Cotabs* and *Medatinic tablets*, 6-29-61. Consent—claimed by Medco Co., Inc., and released under bond for relabeling. *Hy-Jet Wafers*, 7-14-61. Default—destruction.

**6790. Vigosan tablets.** (F.D.C. No. 45898. S. Nos. 32-272/3 R, 32-283/4 R.)

**QUANTITY:** 323 25-tablet btls. and 78 50-tablet btls. at San Juan, P.R.

**SHIPPED:** 3-10-61 and 4-25-61, from New York, N.Y., by Gold Leaf Pharmacal Co., Inc.

**LABEL IN PART:** "Vigosan \* \* \* Gold Leaf Pharmacal Co., Inc., New Rochelle, N.Y. \* \* \* Each tablet contains: Testosterone 2 mgm. Yohimbine HCl. 5 mgm. Vitamin E 10 mgm. Extract Damiana 60 mgm. Extract Nux Vomica 5 mgm. Dosage: One or two tablets 3 times daily."

**LIBELED:** 5-26-61, Dist. P.R.; amended libel 8-22-61.

**CHARGE:** 502(a)—when shipped, the label of the article contained false and misleading representations that the article was adequate and effective as a treatment for stimulating and rejuvenating the male glands and restoring lost vitality and vigor; 502(a)—the listing on the label of the article of yohimbine HCl, vitamin E, extract damiana, and extract nux vomica as active ingredients in the article was false and misleading since such ingredients were not therapeutically active; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 9-21-61. Default—destruction.

**6791. Poly-Hemin capsules.** (F.D.C. No. 45913. S. No. 17-358 R.)

**QUANTITY:** 106 100-capsule btl. at Salt Lake City, Utah, in possession of Brain-Kay-McQuarrie, Inc.

**SHIPPED:** 6-21-60, from Long Island City, N.Y., by Robin Pharmacal Corp.

**LABEL IN PART:** (Btl.) "Poly-Hemin \* \* \* Brain-Kay-McQuarrie, Inc. Salt Lake City, Utah Each Tablet contains: \* \* \* Folic Acid 1 mg. \* \* \* Dosage, Average adult dose one or two capsules daily with meals."

**ACCOMPANYING LABELING:** 4,500 additional bottle labels.

**RESULTS OF INVESTIGATION:** The dealer had supplied the shipper with the labels for the article.

**LIBELED:** 6-9-61, Dist. Utah.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of anemias; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 9-11-61. Default—destruction.

## **DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

### **DRUGS FOR HUMAN USE\***

**6792. Amphetamine sulfate tablets and pentobarbital sodium capsules.** (F.D.C. No. 45743. S. Nos 70-363/4 R.)

**QUANTITY:** Unknown quantities of tablets and capsules at Bangor, Maine, in possession of George H. Horton, M.D.

**SHIPPED:** Prior to 4-24-61, from outside the State of Maine.

**LIBELED:** 4-25-61, Dist. Maine.

**CHARGE:** 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from that requirement since they were prescription drugs which were not used or dispensed by the practitioner in the course of his professional practice.

**DISPOSITION:** 10-30-61. Default—destruction.

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\*See also Nos. 6781-6783, 6785, 6786.